

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

LISTING OF CLAIMS:

1. (CURRENTLY AMENDED) A process for producing an iron-dextran compound, in which the molecular weight of a dextran is reduced by hydrolysis, and functional aldehyde terminal groups thereof converted into alcohol groups by hydrogenation; said dextran as an aqueous solution is combined with at least one water-soluble ferric salt; base is added to the resulting solution to form ferric hydroxide, and the resulting mixture is heated to transform the ferric hydroxide into ferric oxyhydroxide as an association compound with the dextran, characterized in that the hydrogenation is only partial, leaving at the most 15% by weight reducing sugar, calculated on the total amount of carbon hydrates, and said dextran before being combined with the ferric salt, and after being subjected to hydrogenation is subjected to an oxidation, said hydrogenation and oxidation being performed to obtain dextran having substantially all aldehyde groups converted into alcohol and carboxylic groups, said so transformed dextran having no functional aldehyde groups or carboxylic acid groups in the intermediate glycosyl groups;

wherein the hydrogenation is performed by means of sodium borohydride in aqueous solution; and

wherein the oxidation is performed by means of a sodium hypochlorite in basic aqueous solution.

2. (ORIGINAL) A process according to claim 1, characterized in that the dextran before being combined with the at least one ferric salt has a weight mean molecular weight less than 7,000 Da.

3. (PREVIOUSLY PRESENTED) A process according to claim 1, characterized in that after the hydrolysis, but before being combined with the water-soluble ferric salt, the dextran is purified by one or more membrane separations having a cut-off value suitable for holding back dextran molecules above 2,700 Da.

4. (PREVIOUSLY PRESENTED) A process according to claim 1, characterized in that the dextran molecules have a reducing sugar content not above 4% b.w. after the oxidation.

5. (CANCELED).

6. (CANCELED).

7. (PREVIOUSLY PRESENTED) A process according to claim 1, characterized in the following steps:

preparing an aqueous solution comprising the hydrogenated and oxidized dextran and at least one water-soluble ferric salt;

adjusting the pH of said aqueous solution to a value above 10 by addition of a base;
heating the mixture to a temperature above 100°C until it turns into a black or dark brown
colloidal solution and is filterable through a 0.45 µm filter; and
purification and stabilization of the solution using filtration, heating and membrane
separations and addition of one or more stabilizers.

8. (PREVIOUSLY PRESENTED) A process according to claim 7, characterized in that the
stabilization comprises addition of at least one salt of an organic hydroxy acid.

9. (CURRENTLY AMENDED) A process for producing a dextran preparation, in which
process the molecular weight of a dextran is reduced by hydrolysis, and functional aldehyde
terminal groups thereof converted into alcohol groups by hydrogenation; characterized in that the
hydrogenation is only partial, leaving at the most 15% by weight reducing sugar, calculated on
the total amount of carbon hydrates, and said dextran is subsequently subjected to oxidation, said
hydrogenation and oxidation being performed to obtain dextran having substantially all aldehyde
groups converted into alcohol and carboxylic groups, and said dextran product having no
functional aldehyde groups or functional carboxylic acid groups in the intermediate glycosyl
groups;

wherein the hydrogenation is performed by means of sodium borohydride in aqueous
solution; and

wherein the oxidation is performed by means of a sodium hypochlorite in basic aqueous solution.

10. (PREVIOUSLY PRESENTED) Iron-dextran compound produced according to claim 1, characterized in that its apparent peak molecular weight (Mp) is 50,000-150,000 Da and its iron content is 15-45% b.w.

11. (ORIGINAL) Dextran preparation obtainable by a process according to claim 9.

12. (ORIGINAL) Dextran preparation according to claim 11, obtained by a process according to claim 9.

13. (ORIGINAL) A pharmaceutical composition for prophylaxis or treatment of iron-deficiency by parental administration comprising a compound according to claim 10.

14. (PREVIOUSLY PRESENTED) A pharmaceutical composition according to claim 13, further comprising a salt of an organic hydroxy acid as stabilizer.

15. (PREVIOUSLY PRESENTED) A method of preparing a parenterally administrable therapeutical composition using an iron-dextran compound according to claim 10 for prophylaxis or treatment of iron-deficiency, said method comprising the following steps:

providing the iron-dextran compound as an aqueous solution; and
sterilizing the composition.

16. (PREVIOUSLY PRESENTED) A method of producing an iron-dextran compound using a dextran preparation obtainable by the process according to claim 9, in a process, said method comprising the following steps:

mixing the dextran preparation as an aqueous solution with at least one water soluble ferric salt;

heating the mixture to a temperature above 100 C until said mixture turns into a colloidal solution that can be filtered through a 0.45 μ m filter; and
purification of the solution.

17. (PREVIOUSLY PRESENTED) The process for producing a dextran preparation according to claim 9, wherein the dextran has a molecular weight less than 7,000 Daltons.

18. (PREVIOUSLY PRESENTED) The process for producing a dextran preparation according to claim 17, wherein the dextran is purified by one or more membrane separations having a cut-off value suitable for holding back dextran molecules above 2,700 Daltons.

19. (PREVIOUSLY PRESENTED) The process for producing a dextran preparation according to claim 18, wherein the process further comprises further hydrolysis, and one or more separations having a cut-off value between 340 and 800 Daltons removing the smaller molecules.

20. (PREVIOUSLY PRESENTED) The process for producing a dextran preparation according to claim 9, wherein the dextran preparation has a reduced sugar content not above 4% b.w. after the oxidation.

21. (CANCELED).

22. (CANCELED).

23. (CANCELED).

24. (PREVIOUSLY PRESENTED) The process according to claim 3, followed by further hydrolysis and one or more membrane separations having a cut-off value between 340 and 800 Da removing the smaller molecules.

25. (PREVIOUSLY PRESENTED) A process according to claim 1, characterized in that the oxidation is performed by means of a sodium hypochlorite in basic aqueous solution.

26. (PREVIOUSLY PRESENTED) A process according to claim 7, further comprising drying the solution to obtain the desired iron-dextran compound as a stable powder.

27. (PREVIOUSLY PRESENTED) A process according to claim 7, characterized in that the stabilization comprises addition of at least one salt of an organic hydroxy acid selected from the group comprising citrates and gluconates.

28. (PREVIOUSLY PRESENTED) A pharmaceutical composition according to claim 13, further comprising a salt of an organic hydroxy acid selected from the group comprising citrates and gluconates as stabilizer.

29. (PREVIOUSLY PRESENTED) Iron-dextran compound produced according to claim 1, characterized in that its apparent peak molecular weight (Mp) is 70,000-130,000 Da and its iron content is 15-45% b.w.

30. (PREVIOUSLY PRESENTED) Iron-dextran compound produced according to claim 1, characterized in that its apparent peak molecular weight (Mp) is 80,000-120,000 Da and its iron content is 15-45% b.w.

31. (PREVIOUSLY PRESENTED) The method according to claim 15, further comprising adding salt of an organic hydroxy acid to said compound.

32. (PREVIOUSLY PRESENTED) The method according to claim 15, further comprising adjusting the iron content of the compound through the addition of water.

33. (PREVIOUSLY PRESENTED) The method according to claim 16, further comprising drying the solution to obtain the iron-dextran compound as a stable powder.